HIPAA RULE ONE IMPACT CRITERIA
TOOL DESIGN AND FUNCTION

The HIPAA Policy TAG developed this Impact Criteria Tool to help DSHS administrations determine if, how, and when their Divisions and Programs are impacted by HIPAA's Rule One, Transaction Standards. Future Impact Criteria will be developed for additional Rules. Due to the nature of the rules, this process is iterative, and each rule requires a new analysis.

DSHS administration/divisions/programs (hereafter "programs") will be covered by HIPAA by virtue of being a Covered Entity – a health plan, Clearinghouse, or Provider – or by performing functions for or on behalf of a Covered Entity that would make the program a "Business Associate".

In addition to direct regulation, administrations also need to consider the impact on their "trading partners," the people and organizations that they do business with and serve. If a trading partner must change the way it does business, it may affect the way DSHS works with them. The Impact Criteria addresses only those types of entities that clearly affect DSHS. For example, employer group health plans are not included.

The decision about when Rule One requires you to use a Standard Transaction depends on two deceptively simple questions:

- **Is the transaction initiated by a covered entity and**
- **Is the transaction one for which the Secretary has adopted a standard?**

Section I helps you determine whether your program is a Covered Entity. The regulation's definitions of "Covered Entities" are functional. In other words, the regulation defines an entity, for the most part, by what the entity is doing (its function), not what it is labeled. Section II helps you determine whether your program performs standard transactions. Section III identifies HIPAA implications and issues for DSHS.

Attached to the back of the Impact Criteria we have included a HIPAA Background and Resources page to give you some history and other resources; a GLOSSARY for definitions of key terms; and some of the OFFICIAL COMMENTS to the regulations which provide guidance of particular relevance to DSHS programs in evaluating these rules' impacts.

Please read through all of the impact criteria questions. Your program may be functioning as more than one type of Covered Entity and conducting more than one type of transaction. When you do certain actions, you are functioning as a specific type of entity, and your program must follow the rules for that entity. Additionally, a program may be a Covered Entity with respect to some, but not all of its functions. For example, a DSHS program may perform Clearinghouse functions for covered and non-Covered Entities.

DSHS HIPAA IMPACT CRITERIA – RULE ONE

I. HIPAA-COVERED Entities

Q1. ***Health Plan by Definition? Is your program one or a combination of the following[1]:***

a. Medicaid Program – funded with Title XIX monies

b. CHIP

c. Medicare program under title XVIII

d. Indian Health Service program

☐ **Yes. Your program is a HIPAA Health Plan by definition. Go to Question 2 to see if your program also performs other Health Plan functions.**

☐ **No. Your program may still perform HIPAA Health Plan functions. Go to Question 2.**

Q2. ***Health Plan by function? Does your program provide or pay the cost of medical care?***

a. You provide Medical care when you pay for[2]:

i) Diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body

ii) Transportation primarily for and essential to medical care[3]

iii) Insurance covering medical care.

☐ **Yes. Your program performs HIPAA Health Plan functions. Go to Question 3.**

☐ **No. Your program may still perform HIPAA Health Plan functions. Go to Question 3.**

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[1] 45 CFR 160.103. See Official Comments (appended) for guidance on jointly administered programs.
[2] As defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)
[3] See Official Comments (appended) on Atypical services.

Q3. ***Does your program's function(s) meet one or more of the three Health Plan function exceptions?***

a. Does your program pay for excepted benefits?[4]

b. Is your government-funded program's principal purpose other than providing, or paying the cost of, health care?[5]

c. Is your government-funded program's principal activity the direct provision of health care to persons or making of grants to fund direct provision of health care to persons?

☐ **Yes to (a). That portion of your program that provides or pays for excepted benefits is excluded from the Health Plan definition. Go to Question 4.**

☐ **Yes to (b) or (c). Your program is excluded from the Health Plan definition, though you may be a health care provider. Go to Question 4.**

☐ **No (a), (b) or (c). Your program is not excluded as a Health Plan by these exclusions. Go to Question 4.**

Q4. ***Health Care Provider? Does your program furnish, bill, or get paid for health care, or provide medical or health services <u>and</u> transmit any health information in electronic form in connection with a covered transaction?*** [6]

"Health care" means care, services or supplies related to the health of an individual, including, but not limited to: preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affect the structure or function of the body; and sale or dispensing of a drug, devise, equipment, or other item in accordance with a prescription.

☐ **Yes. Your program is performing health care provider functions regulated by HIPAA. Go to Question 5.**

☐ **No. Your program is not performing HIPAA health care provider functions. Go to Question 5.**

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[4] 45 CFR Parts 160.103 page 1402; Excepted benefits are defined as where medical care is secondary or incidental to other insurance benefits: examples include coverage only for accident, or disability insurance, liability insurance including general and automobile, workers compensation, or other similar insurance…

[5] See Official Comments (appended) for examples for (b) and (c).

[6] 45 CFR 160.103, services defintion at 42 USCS 1395x(u)(s) see also appended list of local code categories.

Q5. ***Health Care Clearinghouse?***

Does your program currently receive health care transactions (regardless of media) from health care providers or other entities, translate the data from one format into another format acceptable to the intended payor or payors, and forward the processed transaction to appropriate payors and clearinghouses?

Examples include any of the following: billing service, repricing company, community health management information system, or community health information system, and "value-added" networks and switches[7]

☐ **Yes. Your program performs HIPAA Health Care Clearinghouse functions. Go to Question 6.**

☐ **No. Your program does not perform HIPAA Health Care Clearinghouse functions. Go to Question 6.**

Q6. ***Business Associate? Does your program perform for, on behalf of ,or assist a Covered Entity with a Covered Function including:***

a. **Claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, repricing; or**

b. **Any transaction or other function or activity regulated by the HIPAA rules?**

c. **Legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, of financial services to or for a covered entity.**[8]

☐ **Yes. Your program performs HIPAA Business Associate functions. Go to Part II.**

☐ **No. Your program does not perform HIPAA Business Associate functions. Go to Part II.**

[7] 45 CFR 160.103
[8] 45 CFR 160.103

If you answered No to all entity questions above, or you are excepted under Question 3 and answered No to all non-health plan entities, your program does not perform functions that make it a covered entity under HIPAA, Rule One. Your program is not directly regulated, but may still have impacts because other programs that you depend on or interact with are regulated.

You can either Go to Section IV (E) and (F) or continue with the rest of the impact criteria tool. We strongly suggest you answer Section II, Standard Transaction questions so that you can assess indirect impacts and have an understanding of the types of transactions that are affected.

II. STANDARD TRANSACTIONS

Q1. ***Health Care Claims or Equivalent Encounter Information[9]. Does your program either send or receive Health Care Provider payment requests, either prospectively or retrospectively, for rendering health services?[10]***

***Note "claims" is broadly defined as a payment request. However, sending or receiving claims or equivalent encounter information from one health plan to another health plan (instead of to or from a provider) is not covered.[11]**

☐ **Yes. Your Program must be capable of conducting this business function as a Standard Transaction for Claims.**

☐ **No. Your program does not need to conduct this business function as a Standard Transaction for Claims.**

☐ **Other. Check here if your program receives data/information from claims or equivalent forms.**

[9] 45 CFR 162.1101
[10] See HCFA's list of local code service categories, appended.
[11] See appended Official Comments, Transaction Examples, example 4.

Q2. ***Eligibility for a Health Plan[12]. Does your program send or receive inquiries from or to Health Care Providers or other Health Plans for any of the following information about an enrollee:***

a. Eligibility to receive health care under a health plan

b. Coverage of health care under a health plan

c. Benefits associated with the benefit plan

☐ **Yes. Your Program must be capable of conducting this business function as a Standard Transaction for Eligibility.**

☐ **No. Your program does not need to conduct this business function as a Standard Transaction for Eligibility.**

☐ **Other. Check here if your program receives data/information from eligibility, coverage, or benefit inquiry forms.**

Q3. ***Referral Certification and Authorization[13]. Does your Program:***

a. Send or receive a request for the review of health care to obtain authorization for the health care

b. Send or receive a request to obtain authorization for referring an individual to another health care provider, or

c. Send or receive a response to (a) or (b)

☐ **Yes. Your Program must be capable of conducting this business function as a Standard Transaction for Referral Certification and Authorization.**

☐ **No. Your program does not need to conduct this business function as a Standard Transaction for Referral Certification and Authorization.**

☐ **Other. Check here if your program receives data/information from authorization forms.**

[12] 45 CFR 162. 1201, See Official Comments (appended) regarding government funded program exceptions.
[13] 45 CFR 162. 1301

Q4. ***Health Care Claim Status[14]. Does your program:***

a. Send or receive inquiries to determine the status of a health care claim, or

b. Send or receive a response about the status of a health care claim

☐ **Yes. Your Program must be capable of conducting this business function as a Standard Transaction for Claim Status.**

☐ **No. Your program does not need to conduct this business function as a Standard Transaction for Claim Status.**

☐ **Other. Check here if your program receives data/information from claim status forms.**

Q5. ***Enrollment and Disenrollment in a Health Plan[15]. Does your program:***

a. Send or receive subscriber enrollment information to a health plan to establish or terminate insurance coverage?

☐ **Yes. Your Program must be capable of conducting this business function as a Standard Transaction for Enrollment and Disenrollment.**

☐ **No. Your program does not need to conduct this business function as a Standard Transaction for Enrollment and Disenrollment.**

☐ **Other. Check here if your program receives data/information from enrollment or disenrollment forms.**

[14] 45 CFR 162.1401
[15] 45 CFR 162.1501

Q6. ***Health Care Payment and Remittance Advise[16]. Does your program:***

a. transmit either of the following to a health care provider's financial institution:

i) Payment

ii) Information about the transfer of funds

iii) Payment processing information

b. Transmit either of the following to a health care provider:

i) Explanation of benefits

ii) Remittance advise

☐ **Yes. Your Program must be capable of conducting this business function as a Standard Transaction for Payment and Remittance Advise.**

☐ **No. Your program does not need to conduct this business function as a Standard Transaction for Payment and Remittance Advise.**

☐ **Other. Check here if your program receives data/information from Payment or Remittance advise forms.**

Q7. ***Health Plan Premium Payments[17]. Does your program transmit the following from the entity arranging health care or providing health care coverage to a health plan:***

a. payment

b. information about the transfer of funds

c. detailed remittance information about individuals for whom premiums are paid

d. payment processing information, including payroll deductions, group premium payments, associated group premium payment information

[16] 45 CFR 162.1601
[17] 45 CFR 162.1701

☐ **Yes. Your Program must be capable of conducting this business function as a Standard Transaction for Premium Payments.**

☐ **No. Your program does not need to conduct this business function as a Standard Transaction for Premium Payments.**

☐ **Other. Check here if your program receives data/information from premium payment forms.**

Q8. ***Coordination of Benefits[18]. Does your program transmit information to a health plan, or if your program is a health plan do you receive information from another entity, for the purpose of determining any shared payment responsibilities of the health plan regarding:***

a. Claims

b. payment information

☐ **Yes. Your Program must be capable of conducting this business function as a Standard Transaction for Coordination of Benefits.**

☐ **No. Your program does not need to conduct this business function as a Standard Transaction for Coordination of Benefits.**

☐ **Other. Check here if your program receives data/information from coordination of benefits forms.**

If you are any type of Covered Entity under Section I, and you perform any of the Standard Transaction defined in Section II, then your program performs "Covered Business Functions."

A Covered Business Function means a business function initiated by a Covered Entity or its Business Associate by means of a *Covered Transaction* for which there is a Standard Transaction.

Go to Section III for an explanation of what implications HIPAA Rule One coverage has for your type of entity, for an explanation of the "gray areas" where the regulation is not clear, and a discussion of the next decision the H-Team must make.

[18] 45 CFR 162.1801

III. RULE ONE - HIPAA ENTITY COVERAGE IMPLICATIONS

A. Health Plans Health Plans must be capable of conducting all 8 Electronic Transaction Standards whether or not your program does these business functions:

1. Currently – Some Health Plans conduct prior authorization using media that is not considered electronic under HIPAA. For example, some Health Plans conduct prior authorization transactions on paper and claims status inquiries by telephone;

2. Differently – Some Health Plans may pay providers prospectively for health services, for example, nursing homes. This is a function for which HIPAA requires retrospective payment using the 837 Transaction Standard; or

3. At all - Some Health Plans may not conduct the managed care transactions such as sending enrollment or premium payments to other managed care plans

Health Plans may use business associates, such as Clearinghouses, to conduct or have the capability of conducting some or all of the 8 Electronic Transaction Standards.

Health Plans and their Providers may continue to do a Covered Business Function by other means as long as the Health Plan has the capability of conducting all 8 Standard Transactions.

Examples: A Health Plan may continue to conduct Prior Authorization on paper and by telephone as long as it has the capability of conducting Prior Authorization electronically using the Standard Transaction.

A Health Plan may continue to conduct vendor payments for waiver services using local codes by paper as long as it has the capability of conducting this claim transaction as a Standard Transaction. Note that the Health Plan should make efforts to ensure that the administrative data collected or reimbursement paid under either the paper transaction or any Standard Transaction for claims that might be submitted are comparable.

B. Health Care Providers

Providers who use paper are not covered. When Providers transmit one of the 8 Covered Transactions electronically, they must comply with the Standard for that

Transaction. When a Provider's Clearinghouse transmits or receives any of the 8 Covered Transactions, the Clearinghouse must comply with the Standard.

Health Plans may require Providers to conduct Transactions electronically by contract.

C. Health Care Clearinghouses

If your Program facilitates any of the 8 Covered Transactions and these are received and/or sent out electronically for a Covered Entity, then HIPAA requires you to convert them to or from the Standard.

> **Example, when you receive Covered Transaction in a standard format, then you must convert it to nonstandard formats. When you receive a nonstandard Transaction you must convert it to the Standard.**

D. Business Associates

Covered Entities must ensure that their Business Associates comply with HIPAA when their Business Associates perform a covered function for or on behalf of the Covered Entity. Therefore, Programs that perform HIPAA Covered Transactions as Business Associates must do so according to the Standards.

> **Example: A Program performing billing services for a Health Plan must comply with the HIPAA Standards for claims.**
>
> **Business associates do not have to be capable of performing all 8 Standard transactions, only the transactions that they contract with the Covered Entity to perform.**

E. Indirect Impacts

Even if your program is not directly affected by HIPAA, you need to consider indirect impacts. Indirect impacts may include:

> **If you receive or store data from a Covered Entity, you may not be able to receive the same data because the Covered Entity will use standard codes and formats that may have different field lengths and properties.**
>
> > **Examples: Medicaid provider number must be crosswalked or converted to the National Provider Identifier.**
>
> **Some codes may no longer be available – for example, Local Codes.**
>
> **If you receive data from a HIPAA Covered Entity, you may have to implement new security and privacy policies in order to continue to receive it.**

F. **Component or Single Entity - *Grey Area***

Most administrations perform at least some health plan or provider functions (or perform functions on behalf of other administrations). After using this tool to preliminarily identify which functions are covered under HIPAA rule one, the H-Team must answer a fundamental question:

- **Is DSHS one Health Plan?**

- **If a Program is a Health Plan because of Medicaid business (by definition) and because of its non-Medicaid business (by function), is it one or two Health Plans?**

- **Is DSHS multiple Health Plans, comprised of programs that each perform their own Health Plan functions?**

If DSHS is one health plan, then DSHS is only required to develop the capability to conduct all Standard Transactions in one place. If DSHS is comprised of many Health Plans, then each individual Health Plan must be capable of conducting all Standard Transactions, and standard transactions must be used when conducting business between health plans.

Comments regarding whether a large, multi-function entity like DSHS is one or multiple Health Plans are not clear. This creates an opportunity for DSHS to review advantages and disadvantages to designating itself as one or many. Official Comments regarding government entities do provide some guidance, and are appended.

HIPAA BACKGROUND AND RESOURCES

HISTORY: The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) 42 USC 1320d, among other changes, added "Administrative Simplification" requirements to the Social Security Act. These requirements are intended to standardize various aspects of health information. The federal regulations implementing Administrative Simplification have begun to be released.

RULE 1: The first rule (Transaction Standards) was issued in August 2000, and must be implemented by October 16, 2002, except for small health plans which have an additional year. The rule contained general regulations and definitions applicable to all rules at 45 CFR 160. The Transaction Standards regulations at 45 CFR 162 require certain organizations called "Covered Entities" to use only the HIPAA Standard codes and formats to conduct Transactions related to health care administration and financing.

RULE 2: The second rule (Privacy) was issued December 28, 2000. It is unclear whether this is on hold due to the Bush Administration's 60 day hold memo. This regulation must be implemented by February 2003, except for small health plan which have an additional year. This regulation, at 45 CFR 164 also changed some of the general provisions in 45 CFR 160. The rule specifies when and how Covered Entities and certain organizations that receive health information may transfer, disclose, protect, and receive consent or authorization from patients regarding this information.

OTHER RULES More regulations are expected later in 2001 and continuing. These regulations may include security of health information, national identifiers, and additional Transaction Standards such as report of first injury and claims attachments.

ADD'TL INFO: The DSHS HIPAA Resource Center is available to assist with additional information and tools, as available; questions regarding this impact criteria, HIPAA, and new rules; cross-administration issues; internal and external communications regarding HIPAA compliance; referrals to internal experts or programs facing similar issues; reference materials; and meeting and training which may be of interest.

The DSHS HIPAA Team provides a forum for entity wide, cross administration, and cross agency issues, as well as general information about HIPAA. Contact information: Jim Stevenson at (360) 902-7829.

GLOSSARY

Business Associate:

Business associates are persons or entities who, on behalf of a Covered Entity, perform or assist in an activity involving use or disclosure of individually identifiable health information or any other function or activity regulated by the HIPAA rules or provides legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services where such services involve disclosure of individually identifiable health information. A Covered Entity may be a Business Associate of another Covered Entity.

Covered entity:

Covered entity means a health plan, health care clearinghouse, or health care provider who transmits any health information electronic form in connection with a covered transaction.

Covered function:

Covered function means those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.

Health care:

Health care is the care, services or supplies related to the health of an individual, including, but not limited to: preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affect the structure or function of the body; and sale or dispensing of a drug, devise, equipment, or other item in accordance with a prescription**.**

Health Care Clearinghouse:

Clearinghouses are public or private entities that process or facilitate processing of health information received from another entity. The clearinghouse receives health care transactions from health care providers or others, translates the data from the given format into one acceptable to the intended payor or other, and forwards the processed transaction.

Clearinghouses include billing service, repricing company, community health management information system, or community health information system, and "value-added" networks and switches when performing the above functions.

Health information:

Health information means any information relating to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual, whether oral or recorded in any form or medium that is created or

received by a covered entity, public health authority, employer, life insurer, school or university.

Health Plan:

Health Plans are an individual or group plan that provides, or pays the cost of, medical care.

(1) Health plan includes the following, singly or in combination:

a. A group health plan, as defined in this section
b. Part A or Part B of the Medicare program under title XVII of the Act.
c. The Medicaid program under title XIX of the Act, 42 USC 1396
d. An issuer of a Medicare supplemental policy
e. The Indian Health Service program
f. An approved State child health plan under title XXI of the Act,
g. The Medicare + Choice program under part C of title XVII of the Act
h. A high risk pool that is a mechanism established under State Law to provide health insurance coverage or comparable coverage to eligible individuals, (see regulation for other non-state related categories).

Health plan excepts programs that pay excepted benefits and government funded programs not listed above whose principal purpose is other than providing, or paying the cost of, health care; or whose principal activity is the direct provision of health care to persons or the making of grants to fund the direct provision of health care to persons.

Health Care Provider:

Health care providers are any person or organization who furnishes, bills, or is paid for medical or health services, or health care in the normal course of business.

Medical Care:

Medical care means diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body; transportation primarily for and essential to medical care; or Insurance covering medical care.

RELEVANT OFFICIAL COMMENTS TO RULE ONE

See Full Text at Federal Register, Volume 65, No. 160 (August 17, 2000) and Federal Register, Volume 65 No. 250 (December 28, 2000).

1. **Atypical Services Comment**
2. **Joint Administration Comment**
3. **Examples of Excepted Government Funded Programs from Health Plan**
4. **Transaction Examples Contained in Official Comments**
5. **Government Entity Comments**
6. **Local Code Category List**

1. Atypical Services Comment

Comment: We received comments both for and against subjecting transactions for certain services to the transaction standards. Some commenters recommended that any service that could be billed to a health plan be required to comply with the standards in order to avoid the need to maintain alternate systems. However, other commenters argued that certain Medicaid services are not insured by any other program, thus, use of the standard is unnecessary...

Response: We agree with commenters that case management is a health care service since it is directly related to the health of an individual and is furnished by health care providers. Case management will, therefore, be subject to the standards.

We recognize that the health care claim and equivalent encounter information standard, with its supporting implementation specification, is capable of supporting claims for atypical services. However, requiring all services potentially paid for by health plans to be billed using the [[Page 50316]] standards would lead to taxi drivers, auto mechanics and carpenters to be regulated as health care providers. Instead, we will use our definition of ''health care'' found at 160.103 to determine whether a particular service is a ''health care'' service or not. Services that are not health care services or supplies under this definition are not required to be claimed using the standard transactions. Thus, claims for non-emergency transportation or carpentry services for housing modifications, if submitted electronically, would not be required to be conducted as standard transactions. As noted above, the standards do support such claims and a health plan may choose to require its atypical service providers to use the standards for its own business purposes.

Those atypical services that meet the definition of health care, however, must be billed using the standard if they are submitted electronically. If there are no specific codes for billing a particular service (for example, there is not yet an approved code set for billing for alternative therapies), or if the standard transactions do not readily support a particular method of presenting an atypical service (for example, roster billing for providing immunizations for an entire school or nursing facility), the health care service providers are urged to work with the appropriate Designated Standard Maintenance Organizations (DSMOs) to develop modifications to the standard and implementation specifications. (See ''I. New and Revised Standards'' in this section of the preamble for a discussion of the DSMOs.) We disagree with the proposal that home and community based waiver services should have a blanket

exemption from the administrative simplification standards. First, Congress explicitly included the Medicaid programs as health plans that are subject to the administrative simplification standards. Second, these waiver programs commonly pay for a mix of health care and non-health care services. State Medicaid agencies with home and community based waivers are not exempt from these standards for transactions relating to health care services or supplies.

2. Joint Administration Comment

Where a public agency is required or authorized by law to administer a health plan jointly with another entity, we consider each agency to be a covered entity with respect to the health plan functions it performs. Unlike private sector health plans, public plans are often required by or expressly authorized by law to jointly administer health programs that meet the definition of "health plan" under this regulation. In some instances the public entity is required or authorized to administer the program with another public agency. In other instances, the public entity is required or authorized to administer the program with a private entity. In either circumstance, we note that joint administration does not meet the definition of 'business associate" in 164.501. Examples of joint administration include state and federal administration of the Medicaid and SCHIP program, or joint administration of a Medicare+Choice plan by the Health Care Financing Administration and the issuer offering the plan.

3. Examples of Excepted Government Funded Programs from Health Plan

Government funded programs that do not have as their principal purpose the provision of, or payment for, the cost of health care, but which do incidentally provide such services are not health plans (for example, programs such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and the Food Stamp Program, which provide or pay for nutritional services, are not considered to be health plans).

Government funded programs that have as their principal purpose the provision of health care, either directly or by grant, are also not considered to be health plans. Examples include the Ryan White Comprehensive AIDS Resources Emergency Act, government funded health centers and immunization programs. We not that some of these may meet the rule's definition of health care provider.

We note that in certain instances eligibility for or enrollment in a health plan that is a government program providing public benefits, such as Medicaid or SCHIP, is determined by an agency other than the agency that administers the program, or individually identifiable health information used to determine enrollment or eligibility in such a plan is collected by an agency other than the agency that administers the health plan. In these cases, we do not consider an agency that is not otherwise a covered entity, such as a local welfare agency, to be a covered entity because it determines eligibility or enrollment or collects enrollment information as authorized by law. We also do not consider the agency to be a business associate when conducting these functions…

4. Transaction Examples Contained in Official Comments

Example 1: Corporation K operates a health plan that is a covered entity under these rules. Corporation K owns a hospital which provides care to patients with coverage under Corporation K's health plan and also provides care to patients with coverage under other health plans. Corporate rules require the hospital to send encounter information electronically to Corporation K identifying the patients covered by the corporate plan and served by the hospital.

(A) Must the transmission of encounter data comply with the standards? Both the health plan and the hospital are covered entities. The hospital is a covered entity because it is conducting covered transactions electronically in compliance with its corporate rules. The electronic submission of encounter data satisfies the definition of the health care claims or equivalent encounter information transaction designated as a standard transaction (see Sec. 162.1101(b)). Therefore, the submission of this encounter data therefore must be a standard transaction.

(B) Must the payments and remittance advices sent from Corporation K's health plan to the hospital be conducted as standard transactions? Corporation K's health plan is covered by the definition of ''health plan,'' the hospital is a covered entity, and the transmission of health care payments and remittance advices is within the scope of the designated transactions (see Sec. 162.1601). The health care payments and remittance advices must be sent as standard transactions.

Example 2: A large multi-state employer provides health benefits on a self-insured basis, thereby establishing a health plan. The health plan contracts with insurance companies in seven states to function as third party administrators to process its employees' health claims in each of those states. The employer's health plan contracts with a data service company to hold the health eligibility information on all its employees. Each of the insurance companies sends eligibility inquiries to the data service company to verify the eligibility of specific employees upon receipt of claims for services provided to those employees or their dependents. (A) Are these eligibility inquiries activities that must be conducted as standard transactions? In this case, each insurance company is not a covered entity in its own right because it is functioning as a third party administrator, which is not a covered entity. However, as a third party administrator (TPA), it is the business associate of a covered entity (the health plan) performing a function for that entity; therefore, assuming that the covered entity is in compliance, the TPA would be required to follow the same rules that are applicable to the covered entity if the covered entity performed the functions itself. The definition for the eligibility for a health plan transaction is an inquiry from a health care provider to a health plan, or from one health plan to another health plan, to determine the eligibility, coverage, or benefits associated with a health plan for a subscriber. In this case, the inquiry is from one business associate of that health plan to another business associate of that same health plan. Therefore, the inquiry does not meet the definition of an eligibility for a [[Page 50318]] health plan transaction, and is not required to be conducted as a standard transaction.

(B) Is an electronic eligibility inquiry from a health care provider to the data service company, to determine whether an employee-patient may receive a particular service, required to be a standard transaction? The health care provider is a covered entity, because it conducts covered electronic transactions. The data service company is the business associate of the employer health plan performing a plan function. Therefore, the activity

meets the definition of the eligibility for a health plan transaction, and both the inquiry and the response must be standard transactions.

Example 3: A pharmacy (a health care provider) contracts with a pharmacy benefits manager (PBM) to forward its claims electronically to health plan Z. Under the contract, the PBM also receives health care payment and remittance advice from health plan Z and forwards them to the pharmacy. (A) Must the submission of claims be standard transactions? The pharmacy is a covered entity electronically submitting, to covered entity health plan Z, health care claims or equivalent encounter information, which are designated transactions (see Sec. 162.1101), through a business associate, the PBM. The claims must be submitted as standard transactions.

(B) Must the explanation of benefits and remittance advice information be sent as a standard transaction? Health plan Z and the health care provider are covered entities conducting one of the designated transactions (see Sec. 162.1601). This transaction, therefore, must be conducted as a standard transaction.

Example 4: A State Medicaid plan enters into a contract with a managed care organization (MCO) to provide services to Medicaid recipients. That organization in turn contracts with different health care providers to render the services.

(A) When a health care provider submits a claim or encounter information electronically to the MCO, is this activity required to be a standard transaction? The entity submitting the information is a health care provider, covered by this rule, and the MCO meets our definition of health plan. The activity is a health care claims or equivalent encounter information transaction designated in this regulation. The transaction must be a standard transaction.

(B) The managed care organization then submits a bill to the State Medicaid agency for payment for all the care given to all the persons covered by that MCO for that month under a capitation agreement. Is this a standard transaction? The MCO is a health plan under the definition of ‘‘health plan’’ in Sec. 160.103. The State Medicaid agency is also a covered entity as a health plan. The activity, however, does not meet the definition of a health care claims or equivalent encounter information transaction. It does not need to be a standard transaction. However, note that the health plan premium payment transaction from the State Medicaid agency to the health plan would have to be conducted as a standard transaction because the State Medicaid agency is a covered entity sending the transaction to another covered entity (the health plan), and the transaction meets the definition of health plan premium payment.

5. Government Entity Comments

Comment: A number of commenters urged that the Secretary define more narrowly what characteristics would make a government program that pays for specific health care services a ‘‘health plan.’’ Commenters asserted that there are a number of state programs that pay for ‘‘health care’’ (as defined in the rule) but that are not health plans. They said that examples include the WIC program (Special Supplemental Nutrition Program for Women, Infants, and Children) which pays or nutritional assessment and counseling, among other services; the AIDS Client Services Program (including AIDS prescription drug payment) under the federal Ryan White Care Act and state law; the distribution of federal family planning funds under Title X of the Public Health Services Act; and the breast and cervical health program which pays for cancer screening in targeted populations. Commenters argued that these are not insurance plans and do not fall within the ‘‘health plan’’ definition’s list of examples, all of

which are either insurance or broad- scope programs of care under a contract or statutory entitlement. However, paragraph (16) in that list opens the door to broader interpretation through the catchall phrase, ''any other individual or group plan that provides or pays for the cost of medical care.'' Commenters assert that clarification is needed. A few commenters stated that other state agencies often work in partnership with the state Medicaid program to implement certain Medicaid benefits, such as maternity support services and prenatal genetics screening. They concluded that while this probably makes parts of the agency the ''business partner'' of a covered entity, they were uncertain whether it also makes the same agency parts a ''health plan'' as well.

Response: We agree with the commenters that clarification is needed as to the rule's application to government programs that pay for health care services. Accordingly, in the final rule we have excepted from the definition of ''health plan'' a government funded program which does not have as its principal purpose the provision of, or payment for, the cost of health care or which has as its principal purpose the provision, either directly or by grant, of health care. For example, the principal purpose of the WIC program is not to provide or pay for the cost of health care, and thus, the WIC program is not a health plan for purposes of this rule. The program of health care services for individuals detained by the INS provides health care directly, and so is not a health plan. Similarly, the family planning program authorized by Title X of the Public Health Service Act pays for care exclusively through grants, and so is not a health plan under this rule. These programs (the grantees under the Title X program) may be or include health care providers and may be covered entities if they conduct standard transactions. We further clarify that, where a public program meets the definition of ''health plan,'' the government agency that administers the program is the covered entity. Where two agencies administer a program jointly, they are both a health plan. For example, both the Health Care Financing Administration and the insurers that offers a Medicare+Choice plan are ''health plans'' with respect to Medicare beneficiaries. An agency that does not administer a program but which provides services for such a program is not a covered entity by virtue of providing such services. Whether an agency providing services is a business associate of the covered entity depends on whether its functions for the covered entity meet the definition of business associate in § 164.501 and, in the example described by this comment, in particular on whether the arrangement falls into the exception in § 164.504(e)(1)(ii)(C) for government agencies that collect eligibility or enrollment information for covered government programs.

Comment: Some commenters expressed support for retaining the category in paragraph (16) of the definition…

Response: As described in the proposed rule, this category implements the language at the beginning of the statutory definition of the term ''health plan'': ''The term 'health plan' means an individual or group plan that provides, or pays the cost of, medical care * * * Such term includes the following, and any combination thereof * * *'' This statutory language is general, not specific, and as such, we are leaving it general in the final rule. However, as described above, we add explicit language which excludes certain ''excepted benefits'' from the definition of ''health plan'' in an effort to clarify which plans are not health plans for the purposes of this rule. Therefore, to the extent that a certain benefits plan or program otherwise meets the definition of ''health plan'' and is not explicitly excepted, that program or plan is considered a ''health plan'' under paragraph (1)(xvii) of the final rule.

Local Code Categories

HCFA collated 37 categories of local codes based on input from states about their current business and the relative codes.

1) Alcohol & Other Drug Abuse (AODA) Treatment NOC
2) Anesthesia
3) Audiology
4) Case Management NOC
5) Children's Rehab Services
6) Chiropractic Services
7) Community Based Services (non-waiver)
8) Day Treatment, Community Service Program, Crisis Intervention
9) Dental
10) Dialysis
11) Drugs
12) Durable Medical Equipment
13) Durable Medical Supplies
14) EPSDT
15) Family Planning
16) FQHC & Rural Health Center/Clinic Services
17) Hearing Aids
18) Home Health, Personal Care & Respiratory Care Services
19) Hospice
20) Hospital
21) Lab
22) Managed Care Program (i.e., capitation payments)
23) Medical Services NOC
24) Mental Health NOC
25) Nursing Home
26) Nursing Services NOC
27) Physical, Occupational and Speech Therapy
28) Podiatry
29) Radiology
30) School Based Services
31) Special Prenatal Care Coordination & Child Care Coordination Services
32) Telemedicine
33) Transportation
34) Vaccines & Immunizations
35) Vision
36) Waiver Programs NOC
37) Miscellaneous – Use this section only if one of the previous 36 categories does not 'fit' your local procedure code.

NOC (Not Otherwise Classified) – Use this category only if there is not a more specific category that the services fit into. For example: Nursing services provided in the home are considered home health services and would be reported under category 18. Nursing services provided in a physician's office (if separately identifiable/billable in your State) would be reported under category 26-Nursing Services NOC.